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K002171
p. 1 of 2

510(k) SUMMARY

Invacare Corporation's
Model LC Series Lift Out Chairs

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
PO Box 4028
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person: Edward A. Kroll
Director, TQM and Regulatory Affairs

Date Prepared: July 12, 2000

Name of Device and Name/Address of Sponsor

Model LC Series Lift Out Chairs

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036-2028
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name

Lift Out Chair

Classification Name

Chair, Electric, Positioning

Predicate Devices

Pride Health Care Inc. TMR48 Lift Chair (K953342) and Invacare Comfort + Lift (K864366)

Intended Use

The intended use of the Invacare Model LC Series Lift Out Chair to assist elderly and/or physically challenged persons, who have difficulty rising from a seated position to a standing position.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Invacare Model LC Series Lift Chairs are electrically powered, motor driven devices designed for use in the home or an extended care environment. Their intended function and use is to raise persons from a seated position to a standing position. They are designed for use by elderly or physically challenged individuals who have difficulty rising to a standing position once seated.

There are four (4) basic models included in the LC Series of Lift Chairs. These are Model 2 Way Lift Chair, Model 3 Way Lift Chair, Model 3 Way Wall Hugger Lift Chair, and the Model 3 Way Extra Wide Lift Chair

All models consist basically of an upholstered chair assembly, which is constructed of wood, and fastened to a lower frame, lifting assembly, which is constructed of welded steel. Additionally, all include a motorized linear actuator which is used to position the chair assembly, and a hand held, push button type pendant control, which is used to engage actuator motion and vary the chair's position.

The Invacare Model LC Lift Chairs have been tested to and meet:

- U.L. 1647 "Standard for Motor-Operated Massage and Exercise Machines".
- U.L. 73 "Standard for Motor Operated Appliances"

The upholstery used has been tested to and meets:

- California TB 117 (Flammability)
- UFAC Fabric Classification (Class I)

B. Substantial Equivalence

The Invacare Model LC Series Lift Out Chairs are substantially equivalent to Pride Health Care Inc. TMR48 Lift Chair (K953342) and Invacare Comfort + Lift (K864366). Each of these products are electrically powered, motor driven, lift out chairs with the same intended function and use which is to assist elderly and/or physically challenged persons to arise from a seated position to a standing position.

PERFORMANCE DATA

The Invacare Model LC Lift Chairs have been tested to and meet:

- U.L. 1647 "Standard for Motor-Operated Massage and Exercise Machines".
- U.L. 73 "Standard for Motor Operated Appliances"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Mr. Edward A. Kroll
Director, TQM and Regulatory Affairs
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125

Re: K002171
Trade Name: Invacare Lift Chair
Regulatory Class: II
Product Code: INO
Dated: July 17, 2000
Received: July 19, 2000

Dear Mr. Kroll:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Barbara Zimmerman for CMW

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): *TBD*

Device Name: Model LC Series Lift Out Chairs

Indications For Use:
To assist elderly and/or physically challenged persons, who have difficulty rising from a seated position to a standing position.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bennett for (MW)
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002171

Prescription Use _____ **OR** **Over-The-Counter Use** X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)